

## **REMARKS**

### **Disposition of Claims**

Applicants have withdrawn claims 11-13, 15-25, 34, and 36-39. Applicants have cancelled claims 9 and 14.

### **Drawings**

Examiners rejections have been noted and Applicants have corrected the drawing and have separately submitted them to the Drawing Review Branch.

### **Claim rejection-35 U.S.C. § 112**

Claims 1, 2, 9, 26, 27, and 34 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states inhibiting implies the stopping of a metabolic process. Usually this is accomplished by the introduction of a compound that has an inhibiting effect, but in this case, “inhibiting the presence of DNA methylation” is actually referring to the selection of those cells in which the “helper virus” is not inserted into a region of the genome that is hyper-methylated, thereby allowing for better transcription of the “helper virus” genes. Therefore, this is not the same as actively interfering with the methylation process by the addition of an inhibitor. Therefore, selection of clones that are not methylated does not equate to inhibiting methylation.

Applicants have amended independent claim 1 to recite “selecting for helper virus containing cells in which the helper virus DNA is not methylated by growing the cells in the presence of a selection agent thereby reducing the presence of methylated helper virus”, thus not equating selection of cells not methylated to inhibiting methylation. Support is found in the specification, for example, on page 23, lines 21-24; page 30, lines 20-25.

Applicants have amended dependent claim 2 to recite “selecting cells not methylated comprises positively selecting helper virus which is functional”, thus not equating selection of cells not methylated to inhibiting methylation. Support is found, for example, on page 30, line 20.

Applicants have amended dependent claim 9 to depend from claim 1 and recite that “growing cells in the presence of the selection agent positively selects for cells in which the 5’ long terminal repeat of the helper virus is not methylated”. Support is found, for example, on page 35, lines 24-25.

Applicants have amended independent claim 26 to recite “selecting for non-methylated helper virus-containing cells thereby decreasing the amount of inactive helper virus present in said vector packaging cell”. This amendment is supported by the application as filed.

Applicants have amended dependent claim 27, to recite “selecting for non-methylated helper virus comprises selecting for functional helper virus”.

Applicants have withdrawn claim 24.

The Examiners states in an advisory action dated February 10, 2003, that specifically the term “favorable vector packaging efficiency” is indefinite because the ordinary artisan would not know when something would be included or excluded from the claim.

Applicants have also amended claim 1 by removing the term “favorable vector packaging efficiency”, thus alleviating this rejection.

#### Claim rejection

The Examiner states in claims 1, 9, 10, and 14, it is not clear if Markush claim format was attended in claims 10 and 14.

Applicants have amended claim 10 by removing the Markush claim format and canceled claim 14, thus alleviating this rejection. Claims 1 and 9 are believed to be in proper format.

Applicants respectfully request this rejection be withdrawn.

Claim rejection-35 U.S.C. § 112

Claim 1 in all dependent claims were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in the base claim.

(a) The Examiner states it is not clear what applicant intends by “sufficiently increasing”. This implies that the method must be compared to another method, yet the claim provides no insight as to which methods are compared in order to make a qualitative assessment that something is “sufficiently increased”.

Applicants have amended the claim by deleting any reference to “sufficiently increasing”, thus alleviating this rejection.

(b) The Examiner questions whether “genome sequence viral structural proteins” is referring to the helper virus comprising viral structural proteins.

Applicants have amended claim 1 from “genome sequence viral structural proteins” to recite “retroviral structural genes” to clarify that this is referring to the helper virus construct. Support for this amendment can be found on page 11, line 27 and page 22, line 12 of the specification.

(c) The Examiner states that from the recitation “and a nucleotide sequence”, it is not clear what nucleotide sequence is being referred to.

Applicants have amended the claim by removing the recitation "and a nucleotide sequence", thus alleviating this rejection.

(d) Next, the Examiner states with regards to the recitation "capable of expressing an introduced viral components", grammatical inconsistencies.

Applicants have amended the claim by deleting this recitation, thus alleviating this rejection.

#### Conclusion

For the foregoing reasons, it is respectfully submitted that the proposed amendments be entered, and with their entry, the application is now in condition for allowance.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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